

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER: BMC Medical Co., Ltd.
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PRODUCT:

Product Category	Product Name	Model	UMDN Code	UMDN Name	Classification	Rule
Masks	Nasal Mask	BMC-NM	12447	Masks	II a	Rule 2 according to annex IX of the MDD
		BMC-NM2				
		NM4				
		N5				
		N5A				
		N5B				
		N5H				
		N5AH				
		N5BH				
	Nasal Pillows Interface	P2				Rule 5 according to annex IX of the MDD
		P2H				
	Nasal Pillows System	BMC-PM				Rule 2 according to annex IX of the MDD
	Full Face Mask	BMC-FM				
		BMC-FM1A				
		BMC-FM2				
		F1B				
		F2 NV1				
		F2 NV2				
		F3				

		F5				
		F5A				

CONFORMITY ASSESSMENT ROUTE: ANNEX II WITHOUT CHAPTER 4

WE BMC MEDICAL CO., LTD. HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBILITY FOR THE DOC.

STANDARDS APPLIED:
ISO 17510:2015, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, ISO 10993-10:2010, EN 62366-1:2015, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, ISO 5367:2014

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTRASSE 65, 80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: 0123

(EC) CERTIFICATE(S): G1 081775 0008 Rev.02

START OF CE-MARKING: 2010-03-03

PLACE, DATE OF ISSUE: BEIJING, 2020-06-12

SIGNATURE: 

NAME: XU JIAN

POSITION: GENERAL MANAGER